Essai Clinique

Généré le 23 avr. 2024 à partir de

Titre	A Phase III, Randomized, Double-blind, Placebo-controlled, Multi-center, International Study of Durvalumab or Durvalumab and Tremelimumab as Consolidation Treatment for Patients With Limited Stage Small Cell Lung Cancer Who Have Not Progressed Following Concurrent Chemoradiation Therapy
Protocole ID	ADRIATIC
ClinicalTrials.gov ID	NCT03703297
Type(s) de cancer	Poumon à petites cellules
Phase	Phase III
Type étude	Traitement
Médicament	Durvalumab ou Durvalumab et Tremelimumab en traitement de consolidation
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Scott Owen
Coordonnateur	Corneille Bashagaluke 514-934-1934 poste 34907
Statut	Actif en recrutement
But étude	This is a Phase III, Randomized, Double-blind, Placebo-controlled, Multi-center, International Study of Durvalumab or Durvalumab and Tremelimumab as Consolidation Treatment for Patients with LS-SCLC Who Have Not Progressed Following Concurrent Chemoradiation Therapy
Critères d'éligibilité	• Histologically or cytologically documented limited-stage small cell lung cancer (stage I-III). • Received 4 cycles of chemotherapy concurrent with radiotherapy, which must be completed within 1 to 42 days prior to randomization and the first dose of IP. Chemotherapy must contain platinum and IV etoposide. Radiotherapy must be either total 60-66 Gy over 6 weeks for the standard QD regimen or total 45 Gy over 3 weeks for hyperfractionated BD schedules. • PCI may be delivered at the discretion of investigator and local standard of care, and must be conducted after the end of cCRT and completed between 1 to 42 days to first dose of IP. • Have not progressed following definitive concurrent chemoradiation 5 .Life expectancy ≥ 12 weeks at Day 1. 6. ECOG 0 or 1 at enrolment.
Critères d'exclusion	• Extensive-stage SCLC • Active or prior documented autoimmune or inflammatory disorders • Uncontrolled intercurrent illness, including but not limited to interstitial lung disease. • Active infection including tuberculosis, HIV, hepatitis B and C • Patients who received sequential chemotherapy and radiotherapy (no overlap of RT with chemotherapy)